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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,451	07/30/2003	Katia Vancompernelle	2676-6045US	5403

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,451

Applicant(s)

VANCOMPERNOLLE, KATIA

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,11-14 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05/01/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1, 2, 11-14, 18-22 are pending in this application. Claims 11-14 have been previously withdrawn from consideration.
2. Claims 1, 2, and 18-22 are under consideration in this Office Action.
3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1, 2, 18-20 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Applicants' arguments filed 05/01/2006 have been fully considered but are not persuasive. Although the prior art recognizes posttranslational modification of proteins by methylglyoxal, the examiner respectfully disagrees with applicants' arguments that the phrase "protein methylglyoxal modifying activity" has specific meaning to one of skill in the art and that the claimed isolated polypeptide has enzymatic activities other than the isomerization of a hemithioacetal.
While applicants argue that the phrase "having protein methylglyoxal modifying activity" encompasses additional enzymatic activity other than the isomerization of hemithioacetal, it is not clear from the specification if the disclosed human glyoxalase I consisting of SEQ ID NO: 1 has other additional enzymatic activities. Example 9 only shows a correlation of increased formation of a MG-derived AGE when TNF is administered to L929 cells. The specification does not show that contacting the disclosed human glyoxalase I consisting of SEQ ID NO: 1 with any protein or polypeptide in the presence of its substrate directly results in a methylglyoxal modified protein or polypeptide. Thus, the metes and bounds of the claim are uncertain.
Amending the claim to recite that the claimed phosphorylated polypeptide comprising the

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amino acid sequence of SEQ ID NO: 1 has glyoxalase I activity may overcome the rejection.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2 and 18-20 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have not addressed this rejection in the RESPONSE TO OFFICE ACTION filed 05/01/2006. This rejection is reproduced below.

The claims are genus claims that are directed toward any phosphorylated protein comprising SEQ ID NO:1 and having any "methylglyoxal modifying activity". The scope of the claims includes many and all types of methylglyoxal modifications which is not limited to the formation of S-D-lactoylglutathione from the hemithioacetal produced by the nonenzymatic conjugation of methylglyoxal and glutathione. The genus is highly variable because a significant number of modifying activities exists.

No patentable weight is given to the process of producing the claimed polypeptide as recited in claims 18 and 20 since there is no structural limitations from the process of producing the claimed polypeptide.

The specification discloses a human glyoxalase I consisting of the amino acid sequence of SEQ ID NO: 1. The specification teaches that the glyoxalase I enzyme of SEQ ID NO: 1 catalyzes the isomerization of the hemithioacetal, produced by the nonenzymatic conjugation of methylglyoxal with glutathione, to S-D-lactoylglutathione (see specification on page 3, paragraph [0006]). However, the specification does not describe the enzyme as having any or additional enzyme activities as encompassed by the recitation of "methylglyoxal modifying activity".

In view of the above considerations, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would

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recognize Applicants were in possession of any phosphorylated protein comprising SEQ ID NO: 1 and having any methylglyoxal modifying activity.

Amending the claim to recite that the polypeptide has glyoxalase I activity may overcome the rejection.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 18, 19, 21, 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ranganathan et al. (J Biol Chem. 1993 Mar 15;268(8):5661-7; reference of record) in view of Pestka et al. (Protein Expr Purif. 1999 Nov;17(2):203-14; reference of record).

Applicants' arguments filed 05/01/2006 have been fully considered but are not persuasive. Applicants' position is that the combination of references cannot make obvious the claims 1, 18, 19, 21, and 22 since it is asserted that their combination is "obvious to try" and that phosphorylation of the claimed glyoxalase I of SEQ ID NO: 1 results in the unexpected result of having methylglyoxal modifying activity. The examiner respectfully disagrees with applicants' position for reasons of record as supplemented below.

The examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references. According to MPEP 2144, it is not necessary that the prior art suggest the combination of references to achieve the same advantage or result discovered by applicants. One of ordinary skill in the art at the time the invention was made would have been motivated to combine the references as stated in the previous Office Action dated 01/26/2006 so that the phosphorylated human glyoxalase I can then be used in a wide variety of applications as taught by Pestka et al. including pharmacokinetics, localization, and diagnostic imaging of the phosphorylated human glyoxalase I, and that introduction of a kinase recognition site allows proteins to keep their essential structure intact.

Glyoxalase I activity falls within the scope of the invention since applicants' state in the

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response filed 05/01/2006 that “methylglyoxal modifying activity” encompasses additional enzymatic activities other than the isomerization of a hemithioacetal. Furthermore, there is no specific limitation stating that the claimed phosphorylated polypeptide of SEQ ID NO: 1 catalyzes the transfer of methylglyoxal to any polypeptide. Thus, the combination of references teaches or suggests all the claim limitations.

If applicants assert unexpected results, a showing of unexpected results must be based on evidence, not argument or speculation. Example 9 of the instant specification only shows a correlation of increased formation of a MG-derived AGE when TNF is administered to L929 cells. The specification does not show that directly contacting the disclosed human glyoxylase I consisting of SEQ ID NO: 1 with any protein or polypeptide in the presence of its substrate directly results in a methylglyoxal modified protein or polypeptide.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER